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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/859,087	05/16/97	HARRISON	D 000475-205

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HM22/1208

EXAMINER

PHAM, M

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

12/08/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

08/858,087

Applicant(s)

HARRISON ET AL.

Examiner

Minh-Quan K. Pham

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 August 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16, 18 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16, 18 and 22-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 17) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

The Reply to the Office Action has been received and entered.

In regard to the declaration submitted under 37 USC § 1.131, it has demonstrated that the invention of claims 16, 18, and 22-26 was reduced to practice prior to the 35 USC § 102(e) date of Okun et al. (US Pat. 5,804,436). However, another reference teaching substantially the same subject matter as Okun et al. and was not cited in the previous office action has been discovered. This reference (Parce et al., US Pat. 5,942,443) has a 35 USC § 102(e) date prior to that of Okun et al., and anticipates the invention of claims 16 and 18, and renders the invention of claims 22-26 obvious (see below).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 recites the limitation "the flow path" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is not clear which flow path the claim refers to, the main flow path, one of the two inlet flow paths, or the outlet flow path.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 16 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Parce et al. (US Pat. 5,942,443).

Parce et al. disclose a microfluidic device and method for high throughput screening wherein cellular response of a test compound or series of test compounds of a flowing suspension of living cells is combined with a concentration of a test compound and directed through a detection zone and a cellular response of the living cells is measured (see column 2, lines 50-67; column 3, lines 1-2; and column 5, lines 38-41). The test compounds can include polysaccharides, small organic or inorganic molecules, biological macromolecules, e.g. peptides, proteins, nucleic acids, or an extract made from biological materials such as bacteria, plants, fungi, or animal cells or tissues (see column 6, lines 60-67; and column 7, lines 1-2). The device comprises a series of intersecting channels fabricated on to a substrate, wherein the channels have very small cross sectional dimensions of about 0.1  $\mu\text{m}$  to about 500 $\mu\text{m}$  (see column 8, lines 43-57). The fluid movements can be accomplished through micropumps, microvalves, and/or electroosmosis (see column 12, lines 11-36). Parce et al. also teach a method of stopping fluid flow through the application of potentials at appropriate reservoirs (see column 15, lines 31-63).

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By disclosing all the limitations of claims 16 and 18, Parce et al. anticipate the invention as claimed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Parce et al. (US Pat. 5,942,443) in view of Tracey et al. (reference of record on PTO-1449).

See above for the disclosure of Parce et al.

Parce et al., however, differ from the claimed invention because they did not show that the cells are lymphocytes.

Tracey et al. disclose micro-machined devices in an analogous art for the purpose of showing devices which may be used in blood cell studies, and specifically shows the use of red blood cells and suggests the extension of the technology to leukocyte (lymphocytes are a subset of leukocytes) cell analysis (see abstract).

Therefore, it would have been obvious to one of ordinary skill the art at the time the invention was made to use lymphocytes in the apparatus and method of Parce et al. because

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erythrocytes and leukocytes can be assayed in microfluidic devices with high reproducibility and precision, as taught by Tracey et al. (see page 759, Conclusions).

Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al. (US Pat. 5,942,443) in view of Tracey et al. (reference of record on PTO-1449) as applied to claim 22 above, and further in view of Wilding et al. ((reference of record on PTO-1449).

See above for the disclosure of Parce et al. in view of Tracey et al.

Parce et al. in view of Tracey et al., however, do not disclose that the flow paths are coated.

Wilding et al. disclose albumin-coated microchannels for the flow of biological fluids (see page 44, second column, second paragraph).

Therefore, it would have been obvious to one of ordinary skill the art at the time the invention was made to coat the microchannels of Parce et al., as modified by Tracey et al., in order to prevent the attachment of other proteins to the wall of the channel. This method of preventing the attachment of proteins to the wall of channels is well known in the art and generally referred to as blocking.

### ***Conclusion***

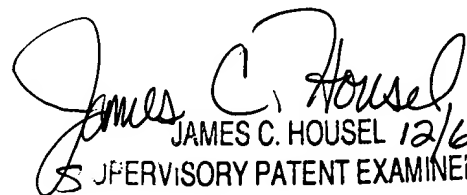
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Quan K. Pham whose telephone number is (703) 305-1444. The examiner can normally be reached on Monday to Friday, 8 AM - 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached at (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Minh-Quan K. Pham, Ph.D.  
December 6, 1999

  
JAMES C. HOUSEL 12/6/99  
SUPERVISORY PATENT EXAMINER